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EFFICACY AND SAFETY OF TAPENTADOL EXTENDED RELEASE VERSUS OXYCODONE CONTROLLED RELEASE IN OPIOID-NAIVE AND OPIOID-EXPERIENCED PATIENTS WITH CHRONIC PAIN ASSOCIATED WITH OSTEOARTHRITIS OF THE KNEE

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Purpose: To characterize the differential efficacy and safety of tapentadol extended release (ER) by prior opioid experience in patients with moderate to severe chronic osteoarthritis knee pain.
Methods: Patients were randomized to receive controlled, adjustable bid doses of tapentadol ER (100-250 mg), oxycodone HCl controlled release (CR; 20-50 mg), or placebo during a 12-week maintenance period preceded by a 3-week titration period. Patients were categorized by prior opioid use during the 3 months before screening. Change from baseline in average pain intensity was assessed (11-point numerical rating scale) for the overall maintenance period. Last observation carried forward was used to impute pain measurements that were missing after discontinuation of treatment.
Results: Opioid-naive patients represented 67.6% of the intent-to-treat population (n = 1,023). The least squares mean difference (LSMD; standard error of the mean [SEM]) from baseline in average pain intensity over the maintenance period in the opioid-naive groups was statistically superior to placebo with tapentadol ER (-0.7 [0.21]; *P*=0.001) but not with oxycodone CR (-0.3 [0.21]; *P*=0.139). Results were similar in the opioid-experienced groups (tapentadol ER vs placebo, LSMD [SEM] = -0.8 [0.32], *P*=0.014; oxycodone CR vs placebo, LSMD [SEM] = -0.5 [0.32], *P*=0.101). The rate of study discontinuation was lower in the tapentadol ER group than in the oxycodone CR group for opioid-naive (placebo, 35.0%; tapentadol ER, 41.7%; oxycodone CR, 68.8%) and opioid-experienced (placebo, 45.6%; tapentadol ER, 45.0%; oxycodone CR, 55.6%) patients. Rates of discontinuation due to adverse events (AEs) were as follows: for opioid-naive patients, placebo, 7.2%; tapentadol ER, 19.6%; oxycodone CR, 48.3%; for opioid-experienced patients, placebo, 5.3%; tapentadol ER, 18.3%; oxycodone CR, 31.5%. The incidence of overall and gastrointestinal-related treatment-emergent AEs were lower in the tapentadol ER group than in the oxycodone CR group, regardless of prior opioid experience (Table 1).
Conclusions: Tapentadol ER (100-250 mg bid) is an effective analgesic treatment with better overall and gastrointestinal tolerability than oxycodone CR (20-50 mg bid), regardless of prior opioid experience.

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ACCEPTABILITY OF A NOVEL 7 DAY BIMONTHLY PARTICIPANT DIARY IN A LONG-TERM CLINICAL TRIAL AMONG PEOPLE WITH SYMPTOMATIC KNEE OA

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Purpose: To evaluate the participant acceptability of a cost-effective novel participant diary engineered to regularly capture relevant clinical outcomes and health economic data during the course of a long-term clinical trial.
Methods: A novel Participant Diary was developed for participants of a two year clinical trial evaluating the benefits of glucosamine, with or without chondroitin, in people with symptomatic knee osteoarthritis (OA). The Participant Diary was dispatched with the study treatment capsules every two months. The seven day diary required the daily recording of knee pain 'at its worst' (rated 0-10), overall global assessment of arthritis (excellent to poor; 0-4), participation in at least moderate physical activity for more than 20 minutes (yes/no), use of analgesia (name; daily

Abstract 328 – Table 1. TEAEs by Prior Opioid Experience

	Opioid-naive			Opioid-experienced		
	Placebo n=223	Tapentadol ER n=235	Oxycodone CR n=234	Placebo n=114	Tapentadol ER n=109	Oxycodone CR n=108
All TEAEs (%)	61.0	79.6	87.2	61.4	67.9	88.0
Gastrointestinal-related	25.6	47.7	67.5	27.2	33.0	66.7
Nervous system-related	24.2	43.4	50.0	26.3	33.0	43.5
Skin and subcutaneous tissue-related	3.1	13.6	22.2	4.4	16.5	17.6
Psychiatric-related	4.5	12.3	16.2	5.3	12.8	12.0
Musculoskeletal and connective tissue-related	17.9	9.8	9.4	16.7	11.9	13.0

TEAEs, treatment-emergent adverse events; ER, extended release; CR, controlled release.